

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Andrew McMichael, Adrian V.S. Hill, Sarah C. Gilbert, Jörg Schneider,  
Magdalena Plebanski, Tomas Hanke, Geoffrey L. Smith and Tom Blanchard

Application No.: 10/686,943 Group: 1648

Filed: October 16, 2003 Examiner: Louise Humphrey, Ph.D.

Confirmation No.: 4585

METHODS AND REAGENTS FOR VACCINATION WHICH GENERATE  
A CD8 T CELL IMMUNE RESPONSE



CERTIFICATE OF MAILING OR TRANSMISSION	
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**FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Fourth Supplemental Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☒ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☒ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application file.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

*Applies to original applications (other than design) filed on or after May 29, 2000*

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is a Listing of References:
- ☒ Copies of the cited references, B11, B12 and C63-C89, are enclosed.
- ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.



Applicant requests that the following non-published pending applications be considered:  
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date



A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.



A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:



A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.



Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

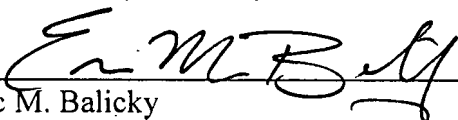


Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By

  
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Dated:

September 4, 2007

Substitute for form 1449B/PTO

**FOURTH SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT  
IN AN APPLICATION**

**LISTING OF REFERENCES**

**SEPTEMBER 4, 2007**

(Use several sheets if necessary)

ATTORNEY DOCKET NO.  
2907.1000-003

APPLICATION NO.  
10/686,943

FIRST NAMED INVENTOR  
Andrew McMichael

FILING DATE  
October 16, 2003

EXAMINER  
Louise Humphrey,  
Ph.D.

CONFIRMATION NO.  
4585

GROUP  
1648

**U.S. PATENT DOCUMENTS**

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A6	2004/0018177 A1	01-29-2004	Hill, <i>et al.</i>

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO
	B11	WO 02/068654 A3	09-06-2002	Centro de Ingenieria Genetica y Biotecnologia	
	B12	WO 2005/030964 A1	04-07-2005	Oxxon Therapeutics Limited	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

C63	"AIDS Vaccines Trials Dangerous," Isis News No. 11/12, Ho, M., ed., <i>Institute of Science in Society</i> [online], October 2001. Retrieved from the Internet, [retrieved on 2006].
C64	Altman, J.D., and Feinberg, M.B., "HIV Escape: There and Back Again," <i>Nature Med.</i> 10(3): 229-230 (2004).
C65	Borrow, P., <i>et al.</i> , "Virus-Specific CD8 <sup>+</sup> Cytotoxic T-Lymphocyte Activity Associated with Control of Viremia in Primary Human Immunodeficiency Virus Type 1 Infection," <i>J. Virology</i> 68(9): 6103-6110 (1994).
C66	Brander, C. and Walker, B.D., The HLA Class I Restricted CTL Response in HIV-1 Infection: Systematic Identification of Optimal Epitopes. HIV Molecular Immunology Database [online], February 2002 [retrieved on 2006-10-19], Retrieved from the Internet <URL:http://www.hiv-web.lanl.gov>.
C67	Desrosiers, R.C., "Prospects for an AIDS Vaccine," <i>Nature Med.</i> 10(3):221-223 (2004).
C68	Dose-Ranging Study to Evaluate the Safety & Immunogenicity of a HIV Vaccine 732461 in Healthy HIV Seronegative Volunteers [online], February 2007 [retrieved on 2007-03-07], Retrieved from the Internet <URL:http://www.clinicaltrials.gov>.
C69	Fang, Z.-Y., <i>et al.</i> , "Expression of Vaccina E3L and K3L Genes by a Novel Recombinant Canarypox HIV Vaccine Vector Enhances HIV-1 Pseudovirion Production and Inhibits Apoptosis in Human Cells," <i>Virology</i> 291:272-284 (2001).
C70	Friedrich, T.C., <i>et al.</i> , "Reversion of CTL Escape - Variant Immunodeficiency Viruses <i>in vivo</i> ," <i>Nature Med.</i> 10(3):275-281 (2004).

EXAMINER

DATE CONSIDERED

Substitute for form 1449B/PTO  <b>FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>  <b>LISTING OF REFERENCES</b>  <b>SEPTEMBER 4, 2007</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2907.1000-003		APPLICATION NO. 10/686,943	
	FIRST NAMED INVENTOR Andrew McMichael		FILING DATE October 16, 2003	
	EXAMINER Louise Humphrey, Ph.D.	CONFIRMATION NO. 4585	GROUP 1648	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
C71	Hu, S.-L., "Non-Human Primate Models for AIDS Vaccine Research," <i>Curr. Drug Targets Infect. Disord.</i> , 5(2):193-201 (2005).
C72	Huygen, K., <i>et al.</i> , "Immunogenicity and Protective Efficacy of a Tuberculosis DNA Vaccine," <i>Nature Med.</i> 2(8): 893-898 (1996).
C73	Kmieciak, D., <i>et al.</i> , "Enhancement of Cellular and Humoral Immune Responses to Human Immunodeficiency Virus Type 1 Gag and Pol by a G/P-92 Fusion Protein Expressing Highly Immunogenic Gag p17/p24 and Pol p51 Antigens," <i>J. Hum. Virol.</i> 4(6):306-316(2001).
C74	Koziel, M.J., "The Role of Immune Responses in the Pathogenesis of Hepatitis C Virus Infection," <i>J. Viral Hepatitis</i> 4(2):31-41 (1997).
C75	Koziel, M.J. and Walker, B.D., "Characteristics of the Intrahepatic Cytotoxic T Lymphocyte Response in Chronic Hepatitis C Virus Infection," <i>Spriner Seminars in Immunopathology</i> , 19(1):69-83 (1997).
C76	Leslie, A.J., <i>et al.</i> , "HIV Evolution: CTL Escape Mutation and Reversion After Transmission," <i>Nature Med.</i> 10(3):282-289 (2004).
C77	Letvin, N.L., "Progress Toward an HIV Vaccine," <i>Annu. Rev. Med.</i> 56:213-223 (2005).
C78	Matano, T., <i>et al.</i> , "Administration of an Anti-CD8 Monoclonal Antibody Interferes with the Clearance of Chimeric Simian/Human Immunodeficiency Virus during Primary Infections of Rhesus Macaques," <i>J. Virology</i> 72(1): 164-169 (1998).
C79	Picard, O., <i>et al.</i> , "Complication of Intramuscular/Subcutaneous Immune Therapy in Severely Immune-compromised Individuals," <i>J. Acquir. Immune Defic. Syndr.</i> , 4(6):641-643 (1991).
C80	Puig, M., <i>et al.</i> , "CD4+ Immune Escape and Subsequent T-Cell Failure Following Chimpanzee Immunization Against Hepatitis C Virus," <i>Hepatology</i> , 44:736-745 (2006).
C81	Puls, R.L. and Emery, S., "Therapeutic Vaccination against HIV: Current Progress and Future Possibilities," <i>Clin. Sci.</i> , 110(1):59-71 (2006).
C82	Riddell, S.R. and Greenberg, P.D., "Principles for Adoptive T Cell Therapy of Human Viral Diseases," <i>Annu. Rev. Immunol.</i> 13: 545-586 (1995).
C83	Riddell, S.R., <i>et al.</i> "Restoration of Viral Immunity in Immunodeficient Humans by the Adoptive Transfer of T Cell Clones," <i>Science</i> 257 (1992).
C84	Rowland-Jones, S., <i>et al.</i> , "HIV-specific Cytotoxic T-cells in HIV-exposed but Uninfected Gambian Women," <i>Nature Medicine</i> 1(1): 59-64 (1995).
C85	Safety of and Immune Response to a DNA HIV Vaccine (pGA2/JS7) Boosted With a Modified Vaccinia HIV Vaccine (MVA/HIV62) in Healthy Adults. National Institute of Allergy and Infectious Diseases [online], September 2006 [retrieved on 2007-03-07], Retrieved from the Internet <URL: <a href="http://www.clinicaltrials.gov">http://www.clinicaltrials.gov</a> >.

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C86	Safety of and Immune Response to a DNA HIV Vaccine Followed by an Adenoviral Vector HIV Vaccine in Healthy Adults. National Institute of Allergy and Infectious Diseases [online], January 2007 [retrieved on 2007-03-01], Retrieved from the Internet <URL:http://www.clinicaltrials.gov>.	
C87	Smith, C.L., <i>et al.</i> , "Recombinant Modified Vaccinia Ankara Primes Functionally Activated CTL Specific for a Melanoma Tumor Antigen Epitope in Melanoma Patients with a High Risk of Disease Recurrence," <i>Int. J. Cancer</i> 113:259-266 (2005).	
C88	Tonini, T., <i>et al.</i> , "Current Approaches to Developing a Preventative HIV Vaccine," <i>Curr. Opin. Investig. Drugs</i> , 6(2):155-162 (2005).	
C89	Wiley, J.A., <i>et al.</i> , "Production of Interferon- $\gamma$ by Influenza Hemagglutinin-Specific CD8 Effector T Cells Influences the Development of Pulmonary Immunopathology," <i>Am. J. Pathol.</i> 158(1): 119-130 (2001).	

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